K032315

Huntleigh HEALTHCARE

Diagnostic Products Division

NOV 18 2004

Appendix C – 510(k) Summary

Intra Operative Probe – IOP8

Submitter's Name: Ms Audrey A. Witko,
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Name of Device: Intra Operative Probe (IOP8)

Manufactured by: Huntleigh Healthcare Ltd (Diagnostic Products Division)
35, Portmanmoor Road,
Cardiff
South Glamorgan CF24 5HN
Wales, U.K.

Contact Person at Manufacturing Facility:
B.J.Colleypriest
Telephone N°: +44 (0) 2920 485885
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Date summary prepared: 19 November 2003

Classification Name Transducer, Ultrasonic, Diagnostic

Predicate Devices

The IOP8 is substantially equivalent to the Dopplex Surgical Probes (DSP) manufactured by Huntleigh Healthcare, which are no longer in production. The DSP has previously been reviewed by the FDA, and cleared by certificate number K946300. The previous application covered 3 different models viz: IOP10, IOP10A & LOP10. Substantial equivalence for the new IOP8 is claimed against the predicate IOP10A model only.

The applicant IOP8 and its associated PA8 Adapter are only for use with Dopplex devices manufactured by Huntleigh Healthcare Ltd.

Device Description

The IOP8 consists of a small diameter stainless steel tube and an interconnection cable. The tube houses a PZT crystal that is protected by a faceplate. A cable links the IOP8 probe tube to an interconnection adapter (designated PA8) that houses the bi-directional electronics. This adapter in turn connects to a main Doppler unit, which is required to drive the IOP8 / PA8 system.

A connector system at the end of the cable allows the IOP8 to be removed and externally sterilized before use. The interconnection adapter and main Doppler unit(s) are not sterilizable, and remain outside the sterile field.

Product Summary

The IOP8 is a passive, self contained, sterilisable, reusable, PW Doppler pencil probe. It enables easy detection of blood flow in vessels of varying diameters, providing evidence of success in vascular reconstructive procedures, including skin grafting.

The IOP will be located on the surface of vessels to assist in the assessment of blood flow. The probe will not be inserted into vessels and does not contact circulating blood.

A connector system at the end of the cable allows the IOP8 to be removed and externally sterilized. An interconnection adapter, housing the bi-directional electronics, is employed, which connects to the main Doppler unit. When connected in this way, the Hand Held Doppler units operate as if a normal VP8 probe is connected.

The following list outlines the Huntleigh Doppler units that can be used with the IOP8:

- D900
- SD2
- MD2 with waveform recording to Dopplex Printa or Dopplex Reporter running on a computer.
- RD2 with waveform recording to Dopplex Printa or Dopplex Reporter running on a computer.
- MD200 with waveform recording to Dopplex Printa or Dopplex Reporter running on a computer

Accessories

An Interconnection Adapter (PA8) is required to interface between the IOP8 and the Dopplex main unit. This adapter and the Dopplex main unit are not designed to be sterilized and must remain outside the sterile field.

An IV Pole Clamp (Ref № ACC47) is available, that allows the Doppler unit to be conveniently outside the sterile field in a position that permits easy access to the controls and, if used, the LCD display.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2004

Mr. Phillip Morris
Technical Manager
Huntleigh Healthcare, Inc.
Diagnostics Products Division
35 Portmanmoor Road
Cardiff., CF24 5HN
UNITED KINGDOM

Re: K032315
Trade Name: IOP8 Intra Operative Probe
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: October 21, 2004
Received: October 25, 2004

Dear Mr. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following control units intended for use with the IOP8 Intra Operative Probe and the PA8 Adaptor, as described in your premarket notification:

Control Unit Model Number

MD200
SD2
RD2
D900
MD2

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Huntleigh HEALTHCARE

Diagnostic Products Division

Appendix F – Indications For Use Summary

510(k) Number (if known): K032315

Device Name: **Intra Operative Probe (IOP8)**

Indications for Use

The IOP8 is a passive, self contained, sterilizable, reusable, Pulsed Doppler pencil probe. It enables easy detection of blood flow in vessels of varying diameters, providing evidence of success in vascular reconstructive procedures, including skin grafting.

The IOP will be located on the surface of vessels to assist in the assessment of blood flow. The probe will not be inserted into vessels and does not contact circulating blood.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the counter use ___

(Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032315

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The IOP8 is an 8MHz ultrasound probe used in conjunction with a PA8 adaptor and a control unit.

The IOP8/PA8 combination together with a MD200 control unit (K930200) would be used to monitor blood flow intra-operatively.

Typical clinical applications include: Carotid endarterectomy, Femoro-popliteal bypass, In-situ femoro-distal bypass,

Detection of arterio-venus fistulae, Confirmation of renal blood flow following aortic aneurysm repair,

Coronary artery bypass grafts, Renal and hepatic transplantation, intraoperative blood flow monitoring

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032315

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The IOP8 is an 8MHz ultrasound probe used in conjunction with a PA8 adaptor and a control unit. The IOP8/PA8 combination together with a SD2 control unit (K930200) would be used to monitor blood flow intra-operatively. Typical clinical applications include: Carotid endarterectomy, Femoro-popliteal bypass, In-situ femoro-distal bypass, Detection of arterio-venus fistulae, Confirmation of renal blood flow following aortic aneurysm repair, Coronary artery bypass grafts, Renal and hepatic transplantation, intraoperative blood flow monitoring

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032315

Prescription Use (Per 21 CFR 801.109)

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	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
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Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The IOP8 is an 8MHz ultrasound probe used in conjunction with a PA8 adaptor and a control unit. The IOP8/PA8 combination together with a RD2 control unit (K984307) would be used to monitor blood flow intra-operatively. Typical clinical applications include: Carotid endarterectomy, Femoro-popliteal bypass, In-situ femoro-distal bypass, Detection of arterio-venus fistulae, Confirmation of renal blood flow following aortic aneurysm repair, Coronary artery bypass grafts, Renal and hepatic transplantation, intraoperative blood flow monitoring

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K032315

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Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The IOP8 is an 8MHz ultrasound probe used in conjunction with a PA8 adaptor and a control unit. The IOP8/PA8 combination together with a D900 control unit (K900882) would be used to monitor blood flow intra-operatively. Typical clinical applications include: Carotid endarterectomy, Femoro-popliteal bypass, In-situ femoro-distal bypass, Detection of arterio-venus fistulae, Confirmation of renal blood flow following aortic aneurysm repair, Coronary artery bypass grafts, Renal and hepatic transplantation, intraoperative blood flow monitoring

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032315

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
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Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The IOP8 is an 8MHz ultrasound probe used in conjunction with a PA8 adaptor and a control unit. The IOP8/PA8 combination together with a MD2 control unit (K930200) would be used to monitor blood flow intra-operatively. Typical clinical applications include: Carotid endarterectomy, Femoro-popliteal bypass, In-situ femoro-distal bypass, Detection of arterio-venus fistulae, Confirmation of renal blood flow following aortic aneurysm repair, Coronary artery bypass grafts, Renal and hepatic transplantation, intraoperative blood flow monitoring

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030815